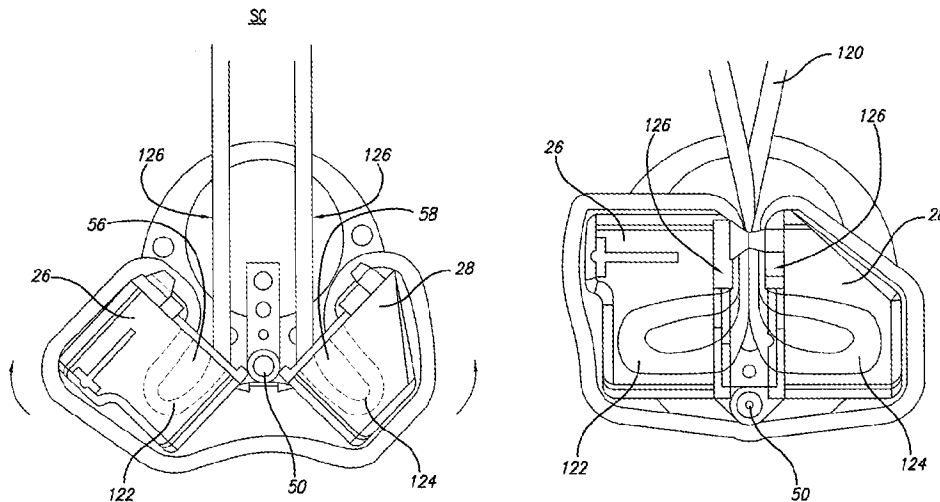


Pre-Appeal Brief Request For Review

In the present application, Claims 44-52 are pending and stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,478,791 ("Carter") in view of U.S. Patent No. 6,592,596 ("Geitz"). The present invention is directed to a method for acquiring tissue in a hollow body organ. Claim 44 is a method claim reciting a series of steps. The Claim is reproduced here for convenience.

44. *A method of acquiring tissue from within a hollow body organ, comprising:*
positioning a first acquisition member and a second acquisition member adjacent to a region of tissue within the hollow body organ, wherein the first and second acquisition members are in apposition to one another along a first longitudinal axis in an open configuration;
adhering tissue from the region within each of the first and second acquisition members;
and
compressing the adhered tissue between the first and second acquisition members in a closed configuration.

Figures 5c and 5d of the present application are illustrative of the last two steps, where tissue 122 is within the tissue acquisition members in 5c and then compressed between the acquisition members in a closed configuration:



Carter

Carter is directed to the provision of therapy for incontinence by selectively reducing an effective length of the endopelvic fascia or other endopelvic support tissues. [Carter, Col. 5,

lines 22-25]. The endopelvic fascia, which is shortened in the procedure outlined by Carter, is described as by Carter as follows:

"Of particular importance for the method of the present invention, endopelvic fascia EF defines a hammock-like structure which extends between the left and right arcus tendinous fascia pelvis ATPF. These latter structures extend substantially between the anterior and posterior portions of the pelvis, so that the endopelvic fascia EF largely defines the pelvic floor." [Col. 5, lines 53 – 59]

Carter depicts the endopelvic fascia in Figure 15a, reproduced here:

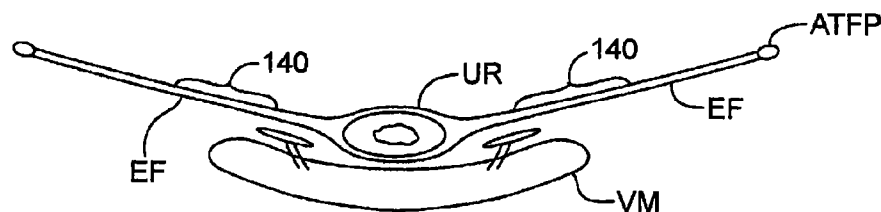


FIG. 15A

As one can see, the endopelvic fascia, **EF**, referred to by Carter as a "hammock-like structure," is a thin tissue stretched between the left and right arcus tendinous fascia pelvis **ATFP**.

The Final Office Action and Advisory Action contends that the first and second acquisition members correspond to arms **52**, and that the steps of "adhering tissue from the region within each of the first and second acquisition members" and "compressing the adhered tissue between the first and second acquisition members" are taught by Figure 9. Applicant respectfully disagreed. The discussion of Figure 9 is set forth in two paragraphs of column 8 of Carter, lines 35 – 51. Carter first states that the arms **52** have roughened surfaces **36** to engage and draw the fascia surface inward. As the tissue is moved inward, the fold retainers **54** push the tissue away from the arms into a fold **22**. The arms **52** act in the same manner as the rollers **36** of Figure 8, gripping the surface of the tissue but not "adhering tissue . . . *within* each of the first and second acquisition members" and not "*compressing the adhered tissue.*"

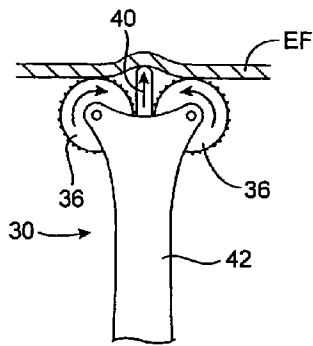


FIG. 8B

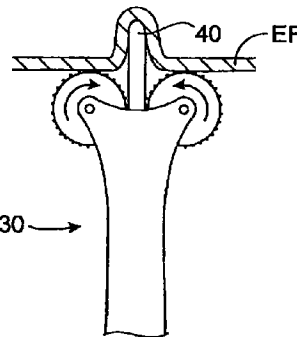


FIG. 8C

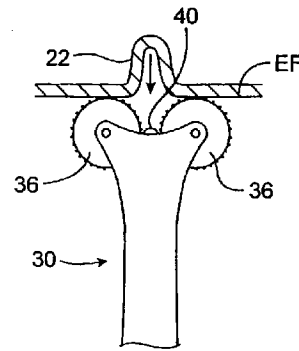


FIG. 8D

Applicant pointed out that Claim 44 requires that the adhered tissue **within each** of the first and second acquisition members. The Advisory Action countered that Carter teaches that the U-shaped channels of Figure 9 receive tissue therein. The Examiner misunderstands the operation of the arms 52. The roughened surface on the edge of the arms bow the tissue away from the U-shaped channels, not into them. As Applicant previously pointed out, that is what the rod 40 does, pushes the tissue away from the device. Carter states:

Arms 52 again have roughened surfaces 36 to engage and draw the fascial surface inward. As the grasping arms close towards each other, roughened fold retainers 54 moved distally relative to shaft 42, thereby urging the tissue surface to form fold 22 in the desired direction. [Col. 8, lines 37-41].

As shown above, tissue fold 22 forms away from the arms, not into them. The Advisory Action provides absolutely no support for the assertion that tissue is received in the U-shaped channels. And the Advisory Action also fails to explain how the distally moving rod 54 allows tissue into the U-shaped channels. If the Office Action was relying on an express teaching of Carter that tissue is received in the U-shaped channels, the Office Action should have specifically identified where Carter teaches this after the Applicant demonstrated that this was not the case. If the Office Action was relying on inherency, then the Office Action should have provided evidence per the requirements of MPEP §2131 that tissue necessarily was received in the U-shaped channels:

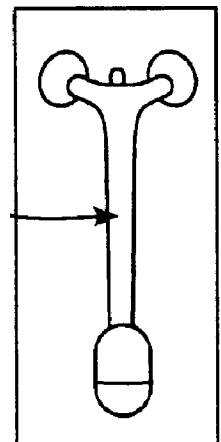
when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

The Final Office Action and the Advisory Action did neither despite the Applicant's demonstration that the rejection was unsound. Specifically, the Applicant stated: "Applicant specifically requested clarification on this issue, stating: If the Office Action contends that any of these limitations are still met by the Carter reference, Applicant respectfully requests that a non-final office action be issued explaining: a) where Carter teaches that the endopelvic fascia tissue is "adher[ed] . . . within each of the first and second" arms **52**; (Applicant contends it is designed and teaches that the tissue is folded away from the arms)"

Instead, the Final Office merely stated without citation or evidence that Carter met the claim limitation. Because this rejection is unsound and unsubstantiated, it is properly withdrawn.

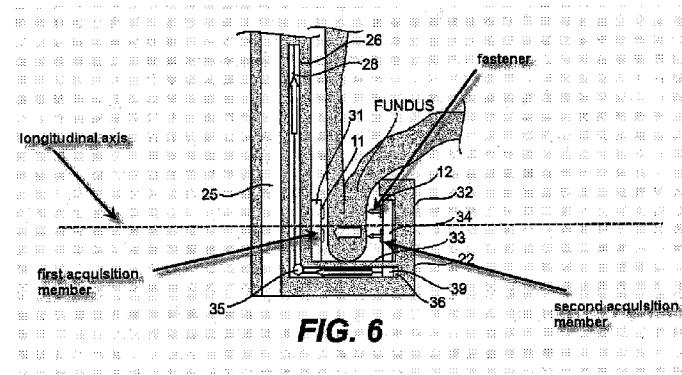
Applicant also appeals the Final Office Action's purported motivation to combine the Carter and Geitz references. Applicant respectfully pointed out the purported inconsistencies that would make the proposed combination non-obvious. In response, the Office Action did not address Applicant's remarks but merely concluded that since both references are to medical devices, it would have been obvious to combine the references. This is not a proper rejection under §103.

Carter's device is a linear device as shown right. Since it is inserted directed through an incision or vaginally directly to the bladder site, there is no change of direction required or contemplated. Conversely, Geitz must handle the problem of being inserted down the esophagus in a first direction, and then reversing direction to apply a tissue fold beyond the gastroesophageal junction. It has a cup-shaped configuration to overcome the problem of how to fold tissue that is not in line with the path of travel of the device.



The difference between the engineering of the two devices is not inconsequential. Applicant contended that they are not compatible, i.e., the teachings of one is inapplicable to the operation of the other. The Office Action countered that "the device of Carter can be used to secure different types of tissues, including the ones taught by Geitz." [Office Action, p. 6]. This is not the standard for obviousness, however. Nor is the standard whether the Office Action can use the Applicant's disclosure as a template for piecing together various prior art to match the claimed invention. Rather, the Office Action must show or explain, with evidence of record, why a person of ordinary skill in the art, armed with the Geitz and Carter references, would have found it obvious to combine them. Applicant respectfully submits that a linear tool like Carter

would never be considered, much less found obvious, for securing tissue in Geitz. For one thing, the Office Action does not explain how the change in direction would be accomplished. That is, how could Carter's linear tool be passed down the esophagus like Geitz (see below) and then change direction 180° and acquire tissue at the bottom of the esophagus while operating in the same manner as Carter teaches? The simple answer is it cannot, because it is designed for a direct, linear approach. There is no advantage, and significant disadvantages, to the proposed combination which negates any suggestion that the combination is obvious. Applicant respectfully submits that a proposed combination of references must be examined for what they teach and what they do before they are blindly combined under the logic that they are both medical devices.



The Supreme Court in KSR International v. Teleflex Inc., which is cited by the Office Action, cautioned against the use of hindsight and analysis that is tailored from the Applicant's disclosure: "A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." The Office Action's rejection appears to be guilty of this very tactic, where two wholly disparate teachings are combined with no rational or proper basis for utilizing the tools of one to solve the problems of the other, other than that it has been held that "use of a known technique (creating fold within a hollow body organ) to improve similar devices (fold for creating devices) will yield predictable results." O.A., p. 4. But Carter does not teach a known technique for folding tissue around a 180° bend as needed by Geitz, so it cannot be substituted for Geitz. The Final Office Action simply ignored how the separate devices work, and instead looked only at the Applicant's claims and how a rejection could be fashioned from the two references. An obviousness rejection must have more of a basis for why these two references were selected and why one of ordinary skill, with no knowledge of the Applicant's disclosure, would have found it obvious to combine the references as suggested by the Office Action. Since this is clearly missing, Applicant respectfully submits that the rejection of Claim 44 is improper and must be withdrawn.